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मानक

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IS 12376-1 (1997): Implants for surgery - Femoral tibial components for partial and total knee joint prostheses, Part 1: Classification, definitions and designation of dimensions [MHD 2: Orthopaedic Instruments, Implants and Accessories]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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भारतीय मानक

शल्यचिकित्सा के लिए अन्तर्रोपण — आंशिक और संपूर्ण
घुटने के जोड़ के लिए फेमोरल एवं टिबियल अवयव

भाग 1 वर्गीकरण, परिभाषाएं और आयामों की नियुक्ति

(पहला पुनरीक्षण)

Indian Standard

IMPLANTS FOR SURGERY — FEMORAL AND
TIBIAL COMPONENTS FOR PARTIAL AND
TOTAL KNEE JOINT PROSTHESES

PART 1 CLASSIFICATION, DEFINITIONS AND DESIGNATION OF DIMENSIONS

(*First Revision*)

ICS 11.040.40

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BUREAU OF INDIAN STANDARDS
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NEW DELHI 110002

NATIONAL FOREWORD

This Indian Standard (Part 1)(First Revision) which is identical with ISO 7207-1 : 1994 'Implants for surgery — Femoral and tibial components for partial and total knee joint prostheses — Part 1 : Classification, definitions and designation of dimensions' issued by the International Organization for Standardization (ISO), was adopted by the Bureau of Indian Standards on the recommendations of Orthopaedic Instruments and Accessories Sectional Committee and approval of the Medical Equipment and Hospital Planning Division Council.

This standard IS 12376 (Part 1) was published in 1987 as dual number standard based on ISO 7207-1 : 1985. Its first revision has been issued to incorporate the modifications effected in the second edition of ISO 7207-1 brought out in 1994. In this revised version a number of definitions have either been replaced or modified with the new definitions to suit the profession. Certain nomenclature have also been changed.

The text of above mentioned ISO standard has been approved as suitable for publication as Indian Standard without deviations. Certain conventions are, however, not identical to those used in Indian Standards. Attention is particularly drawn to the following:

- a) Wherever the words 'International Standard' appear referring to this standard, they should be read as 'Indian Standard'.
- b) Comma (,) has been used as a decimal marker while in Indian Standards, the current practice is to use a point (.) as the decimal marker.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

IMPLANTS FOR SURGERY — FEMORAL AND TIBIAL COMPONENTS FOR PARTIAL AND TOTAL KNEE JOINT PROSTHESES

PART 1 CLASSIFICATION, DEFINITIONS AND DESIGNATION OF DIMENSIONS

(First Revision)

1 Scope

This part of ISO 7207 classifies femoral and tibial components for knee joint prostheses in which one or both bearing surfaces of at least one compartment of the knee are replaced, and gives definitions of components and the designation of dimensions.

Patellar components and prostheses that include an interposed floating component are not included in this part of ISO 7207.

2 Definitions

For the purposes of this part of ISO 7207, the following definitions apply.

2.1 partial unicompartamental knee joint component: Prosthesis designed to replace the bearing surface of one condyle of either the femur or the tibia (see figure 1, position A, B, C or D).

2.2 partial bicompartamental knee joint component: Prosthesis designed to replace the bearing surfaces of both condyles of either the femur or the tibia (see figure 1, positions A and B, or C and D).

NOTE 1 In surgical practice unicondylar components may be used either for unicondylar replacements, for unicompartamental replacements, or for total replacements, whereas generally bicondylar components are used only for total knee joint replacement.

2.3 unicompartamental partial knee joint replacement: Procedure of replacing the bearing surfaces of the contiguous condyles of the femur and tibia in one

compartment of the knee (see figure 1, positions A and C, or B and D).

2.4 total replacement of the knee joint: Procedure of replacing the femoral and tibial bearing surfaces in both compartments of the knee (see figure 1, positions A, B, C and D).

NOTE 2 Provision for articulation with the patella may or may not be provided.

2.5 non-constrained total knee joint prosthesis: Total knee joint prosthesis in which there is no mechanical attachment between the tibial and femoral components and which allows movement in all three planes (see figures 2, 3 and 4).

2.6 partially-constrained total knee joint prosthesis: Total knee joint prosthesis having some mechanical constraint between the tibial and femoral components and which allows movement in more than one plane (see figure 5).

2.7 fully-constrained total knee joint prosthesis: Total knee joint prosthesis in which the two parts are mechanically articulated and which allows movement principally in one plane (see figure 6).

2.8 effective bone resection distance: Minimum distance between resected surfaces of the femur and/or tibia in contact with the plateau(x) of the implant.

2.9 stem: Part of bicondylar component designed to enter the medullary cavity (see figures 2, 5 and 6, dimensions *t* and *f*).

2.10 femoral stem angle: Acute angle between the axis of the femoral stem and the perpendicular to the plateau, as viewed in the antero-posterior direction.

NOTE 3 The direction of this angle determines whether the prosthesis should be used in the right or left leg of the patient.

2.11 tibial stem angle: Acute angle between the axis of the tibial stem and the perpendicular to the plateau, as viewed in the antero-posterior direction.

2.12 intracondylar projection: Portion of condylar component for locating and fixing the component in the condyle (see figures 3 and 4, dimensions t_p and f_p).

2.13 overall width: Maximum dimension in the transverse plane (see figures 2 to 5, dimension w).

2.14 overall depth: Maximum dimension in the antero-posterior plane with the joint fully extended (see figures 2 to 5, dimension d).

2.15 implant plateau: That part of the component in contact with transected bone and/or bone cement.

2.16 bone plateau: Transected surface of the bone which may be in contact with the plateau of the implant and/or bone cement.

2.17 patella bearing surface: Surface that is intended to articulate with the patella or resurfacing component of the patella.

2.18 femorotibial bearing surface: Those areas through which load is transmitted from the femoral to the tibial component.

3 Classification

3.1 Prostheses used to replace some or all of the bearing surfaces in the knee joint shall be classified as follows:

a) unicondylar (see figure 4)

- 1) femoral
- 2) tibial

b) bicondylar (see figures 2, 3, 5 and 6)

- 1) femoral
- 2) tibial

3.2 The intended use of the prostheses shall be classified as follows:

a) partial joint replacement

- 1) unicondylar
- 2) unicompartamental

b) total joint replacement

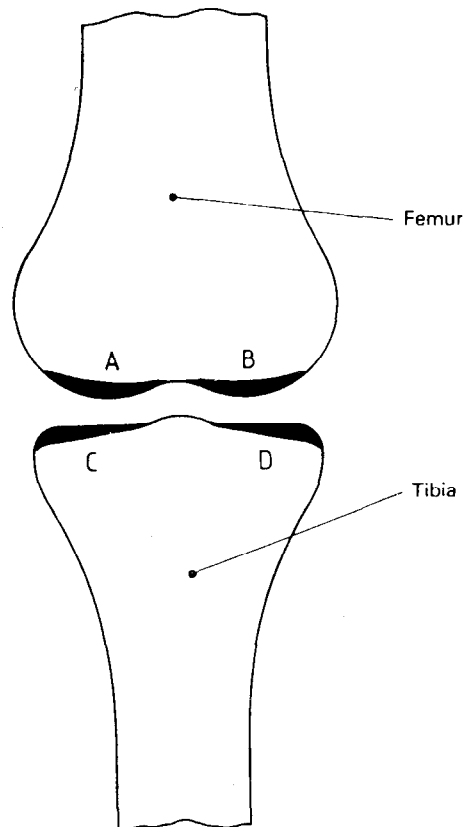
3.3 For total joint replacement the assembled components shall be classified according to the function of the joint in the unloaded condition as follows:

- a) non-constrained (see figures 2, 3 and 4)
- b) partially constrained (see figure 5)
- c) fully constrained (see figure 6)

4 Designation of dimensions

The dimensions of partial and total knee joint prostheses shall be designated in accordance with figures 2, 3, 4 or 5 as appropriate.

NOTE 4 Figures 2 to 6 are intended to be illustrative of typical knee joint prostheses and to designate dimensions and illustrate nomenclature, but representation of the components does not otherwise form part of ISO 7207.

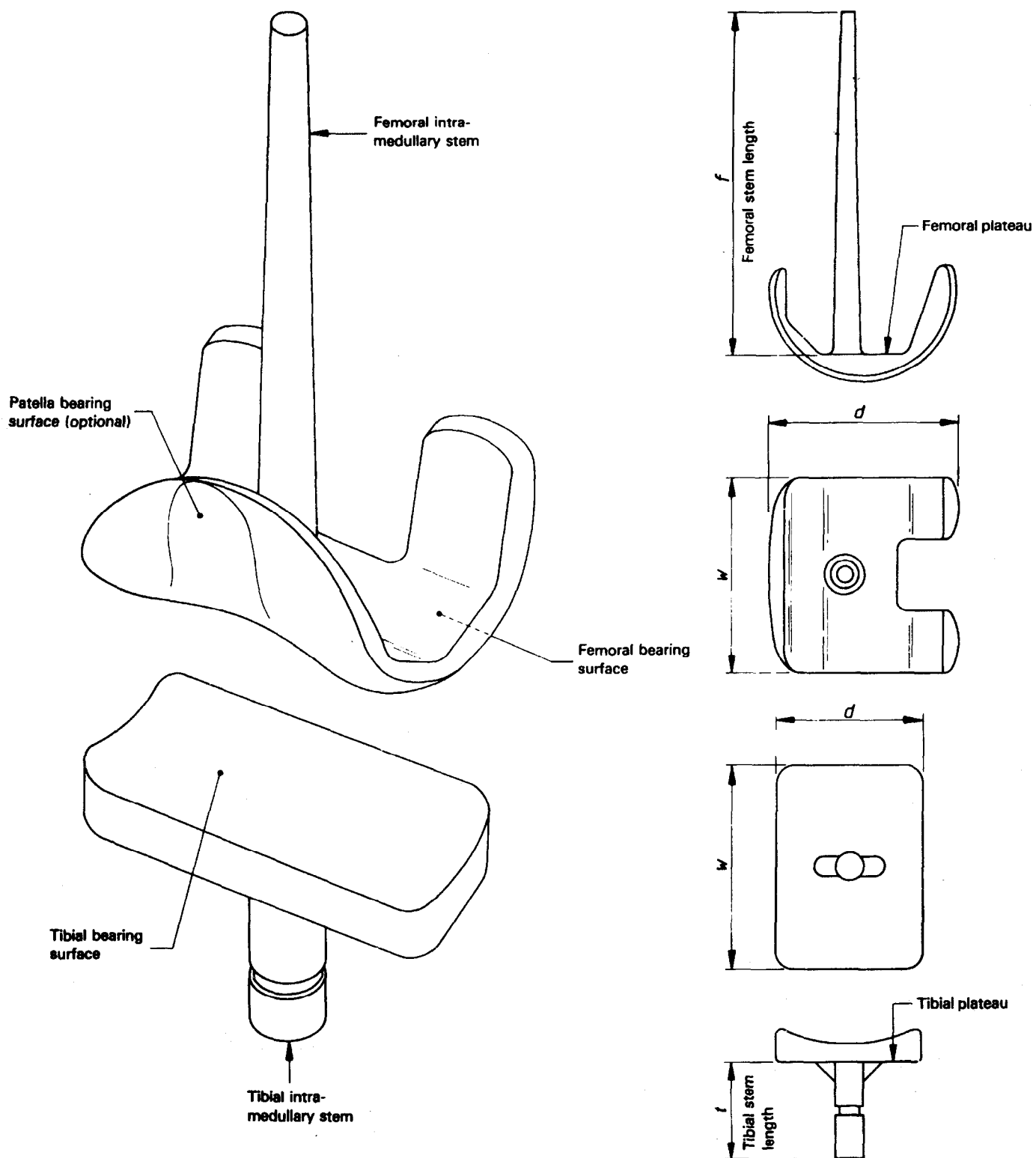


Key:

- A, B Position of condylar prostheses on the femur
- C, D Tibial plateau prostheses

NOTE — These may be medial or lateral.

Figure 1 — Human knee joint showing positions in which condylar prostheses may be used

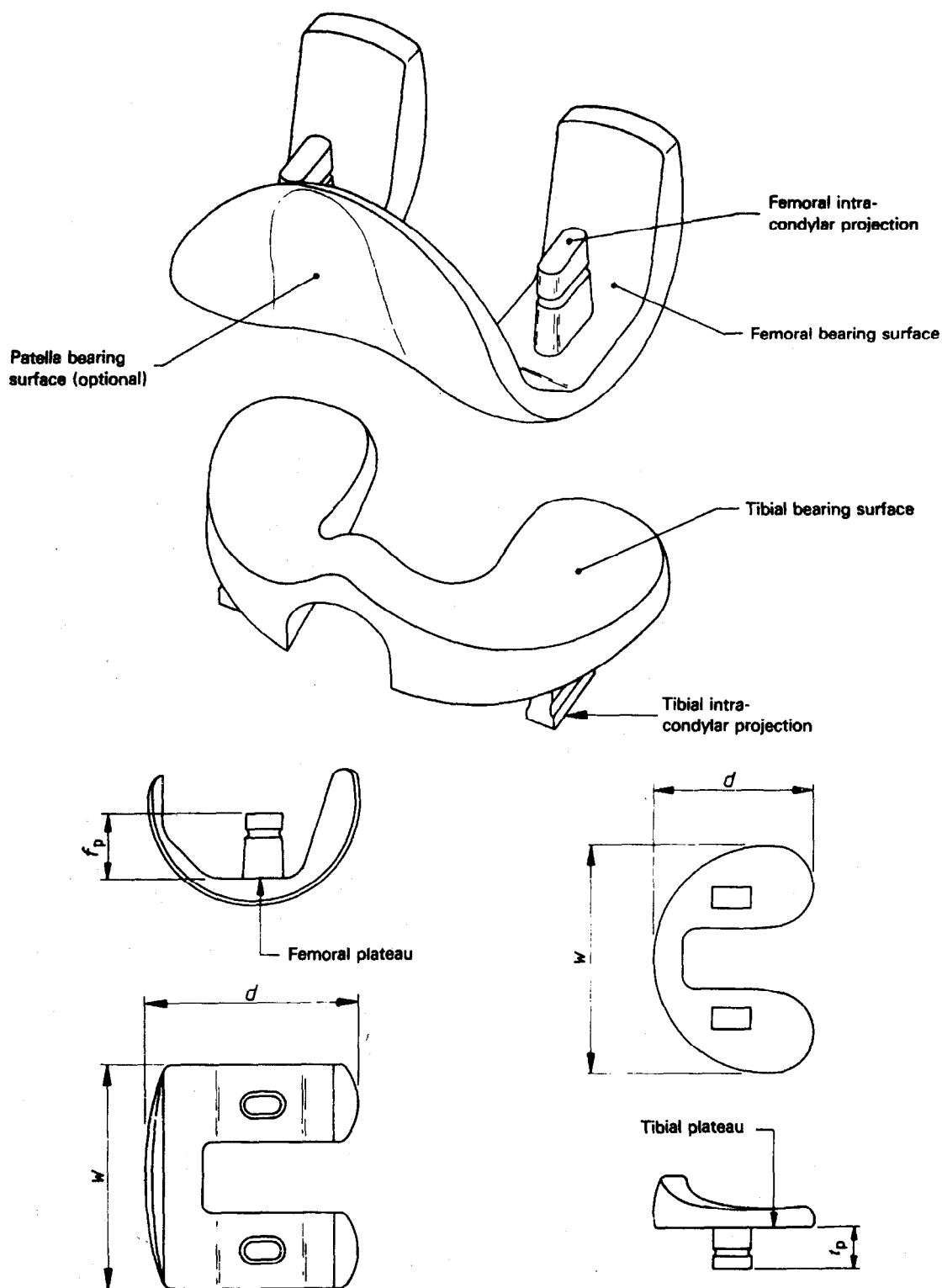


Key:

d overall depth
 f stem (femoral stem length)

t stem (tibial stem length)
 w overall width

Figure 2 — Typical non-constrained bicondylar total knee joint prosthesis with intramedullary stems
(see note 4)



Key:

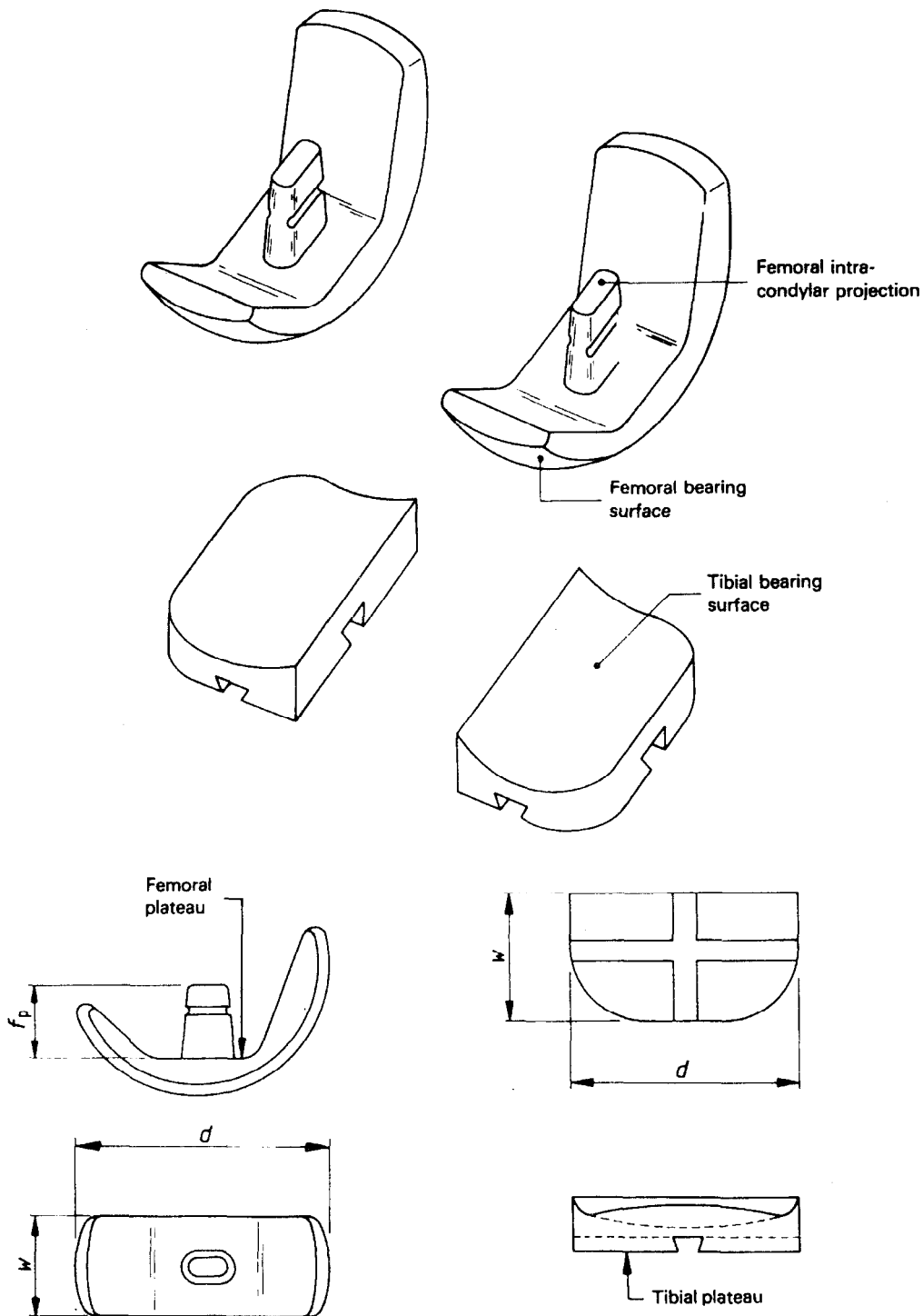
d overall depth

f_p length of femoral intracondylar projection

t_p length of tibial intracondylar projection

w overall width

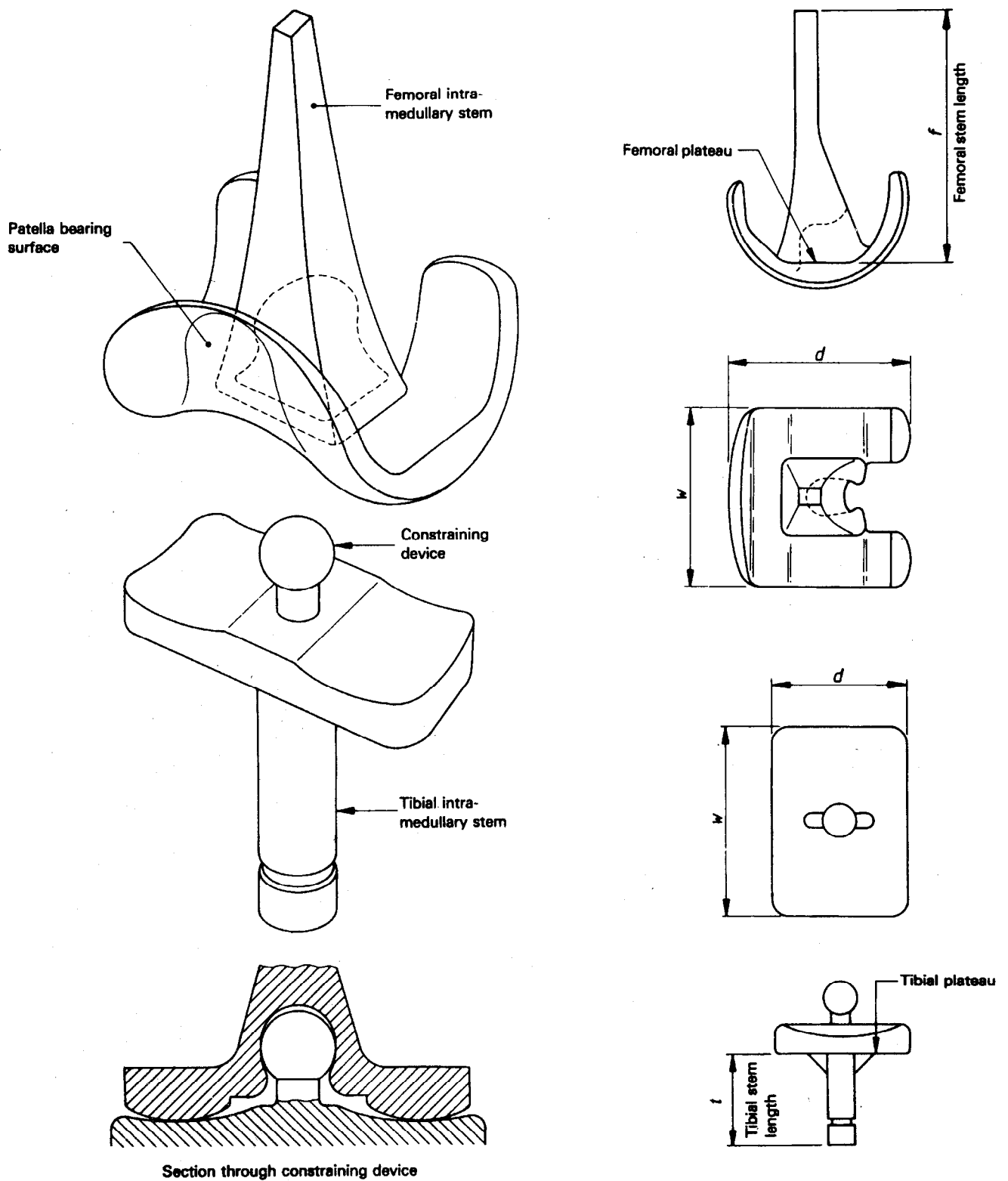
Figure 3 — Typical non-constrained bicondylar total knee joint prosthesis with intracondylar projections, and patella bearing surface (optional) (see note 4)



Key:

- d overall depth
- f_p length of femoral intracondylar projection
- w overall width

Figure 4 — Typical non-constrained unicondylar total knee joint prosthesis (see note 4)



Key:

d overall depth
 f femoral stem length

t tibial stem length
 w overall width

Figure 5 — Typical partially constrained total knee joint prosthesis with intramedullary stems
(see note 4)

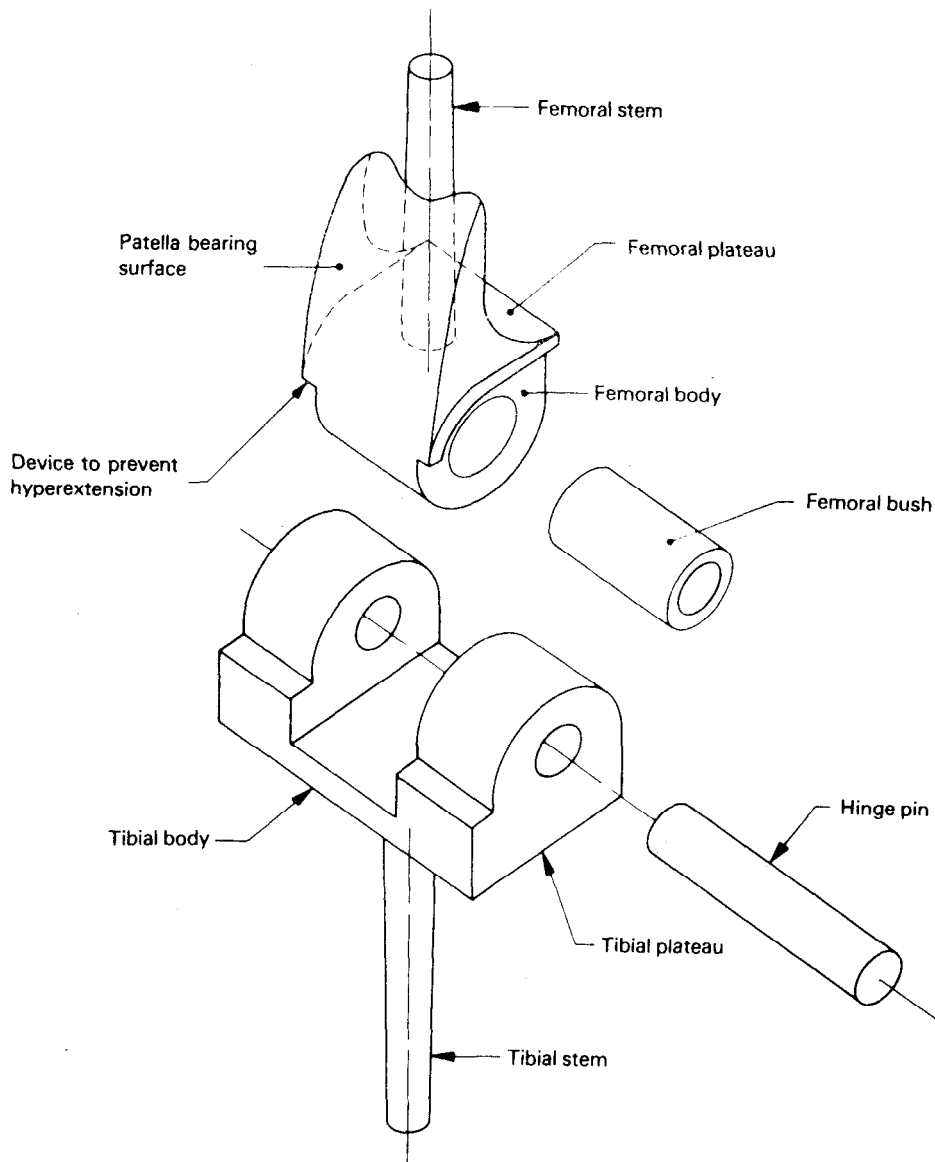


Figure 6 — Typical fully constrained total knee joint prosthesis (see note 4)

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Amendments Issued Since Publication

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